Complete Summary

GUIDELINE TITLE

Recommended colorectal cancer surveillance guidelines by the American Society of Clinical Oncology.

BIBLIOGRAPHIC SOURCE(S)

Benson AB, Desch CE, Flynn PJ, Krause C, Loprinzi CL, Minsky BD, Petrelli NJ, Pfister DG, Smith TJ, Somerfield MR. 2000 update of American Society of Clinical Oncology colorectal cancer surveillance guidelines. J Clin Oncol 2000 Oct 15;18(20):3586-8. [9 references]

Desch CE, Benson AB 3rd, Smith TJ, Flynn PJ, Krause C, Loprinzi CL, Minsky BD, Petrelli NJ, Pfister DG, Somerfield MR. Recommended colorectal cancer surveillance guidelines by the American Society of Clinical Oncology. J Clin Oncol 1999 Apr;17(4):1312-21. [9 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Colorectal cancer

GUIDELINE CATEGORY

Evaluation
Risk Assessment

CLINICAL SPECIALTY

Colon and Rectal Surgery
Oncology

INTENDED USERS

Patients
Physicians

GUIDELINE OBJECTIVE(S)

To determine the most effective, evidence-based, postoperative surveillance strategy for the detection of recurrent colon and rectal cancer.

TARGET POPULATION

Adults previously treated for colon and/or rectal cancer

INTERVENTIONS AND PRACTICES CONSIDERED

Postoperative monitoring of colon and/or rectal cancer, with the following methods:

- History and physical examination
- Carcinoembryonic antigen levels
- Liver function tests
- Fecal occult blood test
- Computed tomography
- Chest x-ray
- Colonoscopy
- Flexible proctosigmoidoscopy for rectal cancer
- Pelvic imaging
- Complete blood cell count

MAJOR OUTCOMES CONSIDERED

- Overall survival
- Disease-free survival
- Quality of life
- Toxicity reduction
- Cost-effectiveness

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Pertinent information from the published literature as of July 1998 was retrieved for the creation of these guidelines. Searches of MEDLINE (National Library of Medicine, Bethesda, MD) and other databases for pertinent articles were

performed. Search words included colon cancer, rectal cancer, follow-up, each specific test considered, cost-effectiveness, and clinical trials. Directed searches were made of the primary articles. In addition, certain authors/investigators were contacted to obtain more recent, unpublished information. Much of the literature on carcinoembryonic antigen testing examined by the ASCO Tumor Marker Guidelines Panel was also relevant. The panel did not review the evidence on carcinoembryonic antigen testing, and instead used the guideline already developed by the ASCO Expert Panel on Tumor Marker Recommendations.

For the 2000 update, computerized literature searches of MEDLINE and CancerLit were performed. The searches of English-language literature from 1997 to 2000 combined the terms colon neoplasms and rectal neoplasms with the term surveillance. The set of articles yielded from this initial search was combined in turn with each of the tests or procedures addressed in the original guideline (e.g., history and physical examination, liver functions test, carcinoembryonic antigen). The searches were limited to human-only studies and clinical trials.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus
Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Level and Type of Evidence

Evidence obtained from meta-analysis of multiple, well-designed, controlled studies. Randomized trials with low false-positive and low false-negative errors (high power)

Evidence obtained from at least one well-designed experimental study. Randomized trials with high false-positive and/or false-negative errors (low power)

Evidence obtained from well-designed, quasiexperimental studies such as non-randomized, controlled, single-group, pre-post, cohort, time, or matched case-control series

Evidence from well-designed, non-experimental studies such as comparative and correlational descriptive and case studies

Evidence from case reports and clinical examples

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

In evaluating the evidence, the panel followed a process for guideline development established by the American College of Chest Physicians. The process included a systematic weighting of the level of the evidence and a systematic grading of the evidence for making a recommendation.

The panel identified topics to be addressed by the guideline, developed a strategy for completion of the guideline, and reviewed the literature. The panel examined both retrospective and prospective studies that evaluated the effectiveness of surveillance testing in detecting recurrence earlier and positively affecting survival. The recommendations made by the expert panel are based on current methods for detecting the recurrence of colorectal cancer. The guidelines were circulated in draft form through several iterations, and all members of the panel had an opportunity to comment on the recommendations.

The experts reviewed the available evidence and added their best clinical judgment to make final recommendations, using standardized language to characterize the strength of the evidence. In accordance wit the ASCO health Services Research Policies and Procedures for Guidelines, "recommendation" was used when there was level I or II evidence and panel consensus. "Suggestion" was used when there was level III, IV or V evidence and panel consensus. "No Guideline possible" was used when there were no data or the panel could not reach a consensus.

For the 2000 update, the expert panel cochairs completed the review and analysis of data published since 1994. The cochairs held a teleconference to consider the evidence for each of the 1999 recommendations.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Consensus Development Based on Evidence

The panel identified topics to be addressed by the guideline, developed a strategy for completion of the guideline, and reviewed the literature. The panel examined both retrospective and prospective studies that evaluated the effectiveness of surveillance testing in detecting recurrence earlier and positively affecting survival. The recommendations made by the expert panel are based on current methods of detecting the recurrence of colorectal cancer. The guidelines were circulated in draft form through several iterations, and all members of the panel had an opportunity to comment on the recommendations.

The panel did not attempt to codify established practice. The experts reviewed the available evidence and added their best clinical judgment to make final recommendations, using standardized language to characterize the strength of the evidence. In accordance with the ASCO Health Services Research Policies and Procedures for guidelines, "recommendation" was used when there was level I or II evidence and panel consensus. "Suggestion" was used when there was level III, IV, or V evidence and panel consensus. "No guideline possible" was used when there were no data or the panel could not reach consensus.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grade of Recommendation

There is evidence of type 1 or consistent findings from multiple studies of type II, III, or IV

There is evidence of type II, III, or IV and findings are generally consistent

There is evidence of type II, III, or IV but findings are inconsistent

There is little or no systematic empirical evidence

COST ANALYSIS

Cost of Follow-Up Surveillance

The findings from studies of postoperative monitoring in colorectal cancer have varied widely. As a result of this uncertainty, there is considerable variation in follow-up practice. The variation in practice has resulted in wide variation in follow-up costs. For example, the differences between Medicare-allowed charges differed 28-fold (from $561 to $16,492 over a 5-year period). As a result of these differences in patterns, costs, and reported outcomes, the American Society of Clinical Oncology (ASCO) convened an expert panel to address the issue of colorectal cancer-related surveillance.

Carcinoembryonic Antigen (CEA) Testing

A study from the Eastern Cooperative Oncology Group followed patients on the INT 0089 trial after surgical resection for high-risk stage B2 and C colon carcinoma. For the 421 patients who developed recurrent disease, investigators tried to determine which tests were the most effective and cost-effective in detecting metastases. Follow-up testing was done by protocol guidelines. Ninety-six of the 421 patients with recurrent disease underwent surgical resection with curative intent. For the subgroup of resectable patients, the first test to detect recurrence was the CEA test (n = 30), chest x-ray (n = 12), colonoscopy (n = 14), and other tests (n = 40). The physician´s examination was unsuccessful in finding resectable disease. The CEA test was the most cost-effective approach to detecting potentially resectable metastases from colon cancer. Another study followed patients with a specified testing strategy after curative colorectal surgery. In this study, 64% of recurrences were detected first by CEA testing, far more than the other tests in the battery.

METHOD OF GUIDELINE VALIDATION

External Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The guidelines were reviewed by three outside experts in gastroenterology, an expert in surgical oncology, and an outside health service researcher.

The 2000 guideline update was circulated in draft form to the full expert panel for review and approval.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

1. Carcinoembryonic Antigen

   Guideline: Note: This guideline was adopted from the ASCO Clinical Practice Guidelines for the Use of Tumors Markers in Breast and Colon Cancer (American Society of Clinical Oncology [ASCO], 1996). If resection of liver metastases would be clinically indicated, it is recommended that postoperative serum carcinoembryonic antigen (CEA) testing be performed every 2 to 3 months in patients with stage II or III disease for >/= 2 years after diagnosis. An elevated CEA level, if confirmed by retesting warrants further evaluation from metastatic disease but does not justify the institution of systemic therapy for presumed metastatic disease.

   Level of Evidence: II

   Grade of Recommendation: C

2. History and Physical Examination

   Guideline: There are no data that directly address the contribution of the history and physical examination to outcomes of colorectal cancer surveillance. However, it is the consensus of the expert panel that a clinical history and pertinent physical examination should be performed every 3 to 6 months for the first 3 years and annually thereafter.

   Level of Evidence: V

   Grade of Recommendation: Panel Consensus

   2000 Recommendation: Clinical history, test coordination, and patient counseling should be performed by the physician every 3 to 6 months for the first 3 years and annually thereafter.

3. Liver Function TestsL

Guideline: The data are sufficient to suggest against the regular monitoring of any liver function tests after primary therapy for colon and rectal cancer.

Level of Evidence: IV

Grade of Recommendation: D, Panel Consensus

4. Fecal Occult Blood Test

   Guideline: The data are sufficient to suggest against periodic fecal occult blood tests in surveillance for colorectal cancer recurrence.

   Level of Evidence: II

   Grade of Recommendation: C

5. Computed Tomography

   Guideline: The data are sufficient to suggest against routine computed tomography scanning in the follow-up of colorectal cancer.

   Level of Evidence: II

   Grade of Recommendation: A

6. Chest X-ray

   Guideline: Note: There was not consensus among panel members on this guideline. One dissenting vote is noted here. Data are sufficient to advise against routine yearly chest x-rays (CXR) in the follow-up of colorectal cancer. CXRs may be ordered to diagnoses abnormalities prompted by elevated CEA levels or for patients who have symptoms suggestive of a pulmonary metastasis.

   Level of Evidence: II

   Grade of Recommendation: B

7. Colonoscopy

   Guideline: All patients should have a colonoscopy for the pre- or perioperative documentation of a cancer- and polyp-free colon. The data are sufficient to recommend colonoscopy every 3 to 5 years to detect new cancers and polyps. Routine annual colonoscopies are not recommended for all patients. The follow-up schema for colorectal screening guidelines, devised by the World Health Organization (WHO) panel for patients with adenomatous polyps, is recommended (Winawer et al., 1995).

   Level of Evidence: I

Grade of Recommendation: B

8. Flexible Protosigmoidoscopy

   Guideline: Combined chemotherapy and pelvic radiation represent the standard treatment for patients with stage II and stage III rectal cancer. For patients who have not received pelvic radiation, either because they could not for medical reasons or because they refused such treatment, direct imaging of the rectum at periodic intervals is suggested. For patients who have received pelvic radiation, direct imaging of the rectum (except colonoscopy at 3 to 5 years) is not suggested. All patients with rectal cancer should have a colonoscopy for the pre- or perioperative documentation of a cancer- and polyp-free colon.

   Level of Evidence: IV

   Grade of Recommendation: C, Panel Consensus

9. Pelvic Imaging

   Guideline: Data are sufficient to suggest against routine pelvic imaging in asymptomatic patients who have received surgical resection and radiation for rectal cancer.

   Level of Evidence: IV

   Grade of Recommendation: D

10. Complete Blood Cell Count

    Guideline: The expert panel advises against routine monitoring of CBC for colorectal cancer surveillance.

    Level of Evidence: V

    Grade of Recommendation: Panel Consensus

Level and type of evidence

Evidence obtained from meta-analysis of multiple, well-designed, controlled studies. Randomized trials with low false-positive and low false-negative errors (high power)

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Grade of Recommendation

There is evidence of type 1 or consistent findings from multiple studies of type II, III, or IV

There is evidence of type II, III, or IV and findings are generally consistent

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CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Postoperative monitoring for colorectal cancer may identify recurrence before symptoms develop, at a stage when another curative resection is still possible and may afford a small survival benefit.

Carcinoembryonic antigen and detection of recurrence: A study from the Eastern Cooperative Oncology Group found that the carcinoembryonic antigen test was the most cost effective approach to detecting potentially resectable metastases from colon cancer. Another study found that 64% of recurrences were first detected by the carcinoembryonic antigen test, far more than the other tests included in the battery.

POTENTIAL HARMS

Carcinoembryonic antigen and false negatives: Approximately 30% of all colorectal cancer recurrences do not produce carcinoembryonic antigen; a false-negative carcinoembryonic antigen is more common in poorly differentiated tumors.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

In formulating recommendations for colorectal cancer surveillance, the American Society of Clinical Oncology (ASCO) considered the tenets of guideline development, emphasizing review of data from controlled clinical trials. However, it is important to realize that guidelines cannot always account for individual variation among patients. They are not intended to supplant physician judgment with respect to particular patients or special clinical situations and cannot be considered inclusive of all proper methods of care or exclusive of other treatments reasonably directed at obtaining the same results. Accordingly, ASCO considers adherence to these guidelines to be voluntary, with the ultimate determination regarding their application to be made by the physician in light of each patient's individual circumstances. In addition, these guidelines describe administration of therapies in clinical practice; they cannot be assumed to apply to interventions performed to the context of clinical trials, given that clinical studies are designed to test innovative and novel therapies in a disease for which better therapy is sorely needed. In that guideline development involves a review and synthesis at the latest literature, a practice guideline also services to identify important questions for further research and those settings in which investigation therapy should be considered.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1999 Apr (revised 2000 Oct)

GUIDELINE DEVELOPER(S)

American Society of Clinical Oncology - Medical Specialty Society

SOURCE(S) OF FUNDING

American Society of Clinical Oncology (ASCO)

GUIDELINE COMMITTEE

Colorectal Cancer Surveillance Panel

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

The panel was composed of experts in clinical medicine, clinical research, outcomes/health services research, and related disciplines (medical decision making, health economics, and quality of life) and medical ethics, with a focus on expertise in colon and rectal cancer. A patient representative was also included on the panel. The clinical experts represented all relevant medical disciplines, including medical oncology, radiation oncology, and surgical oncology. Both academic and community practitioners were included. A steering committee under the auspices of the Health Services Research Committee chose panel participants for the clinical practice guideline development process.

Members: Christopher E. Desch; Al B. Benson III; Thomas J. Smith; Patrick J. Flynn; Carol Krause; Charles L. Loprinzi; Bruce D. Minsky; Nicholas J. Petrelli; David G. Pfister; Mary R. Somerfield.

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All members of the expert panel complied with American Society of Clinical Oncology (ASCO) policy on conflict of interest, which requires disclosure of any

financial or other interest that might be construed as constituting an actual, potential, or apparent conflict. Members of the expert panel completed ASCO's disclosure form and were asked to reveal ties to companies developing products that might potentially be affected by promulgation of the guidelines. Information was requested regarding employment, consultancies, stock ownership, honoraria, research funding, expert testimony, and membership on company advisory committees. The panel made decisions on a case-by-case basis as to whether an individual's role should be limited as a result of a conflict.

GUIDELINE STATUS

This is the current release of the guideline.

An update is not in progress at this time.

GUIDELINE AVAILABILITY

Electronic copies: Available from the American Society for Clinical Oncology (ASCO) Web site.

A previous versions of the guideline is also available from the American Society of Clinical Oncology (ASCO) Web site: Recommended Colorectal Cancer Surveillance Guidelines.

Print copies: Available from American Society of Clinical Oncology, Health Services Research, 1900 Duke Street, Suite 200, Alexandria, VA 22314.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

A document titled "A Patient's Guide: Follow-Up Care for Colorectal Cancer" is available from the American Society for Clinical Oncology (ASCO).

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This summary was completed by ECRI on June 29, 1999. The information was verified by the guideline developer on July 27, 1999. The summary was updated by ECRI in December 2000; the updated summary was verified by the guideline developer as of December 20, 2000.

Date Modified: 11/1/2004